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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,699	03/30/2001	Munehide Kano	50026/022002	7451

21559 7590 11/20/2003

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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/823,699	KANO ET AL.	
	Examin r	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,9,11-20,24,26,28-33,37,39 and 41-61* is/are pending in the application.

4a) Of the above claim(s) *46-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7, 9, 11-20, 24, 26, 28-33, 37, 39, 41-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5/20/03, 8/4/03*
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

The amendment and response filed August 4, 2003 has been entered. Claims 6, 8, 10, 21-23, 25, 27, 34-36, 38, and 40 have been canceled. Claims 1, 5, 7, 9, 11, 16, 17, 20, 24, 29-33, 37, and 42-45 have been amended, claims 46-61 are newly added.

As an initial matter, newly submitted claims 46-61 are directed to a species of an invention that is distinct from the invention originally claimed for the following reasons: the newly submitted claims are drawn to a recombinant Sendai virus lacking an envelop gene, wherein the envelope gene is F gene, which is a species of a recombinant Sendai virus, distinct from the Sendai virus lacking a V gene. The claims would have been restricted if they were originally presented.

Since applicant has received two actions on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 46-61 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 1-5, 7, 9, 11-20, 24, 26, 28-33, 37, 39, 41-45 are under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in 8/4/04 response would be addressed to the extent that they apply to current rejection.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on May 20 & August 4, 2003 respectively are acknowledged. The submission is in compliance with the provisions of 37 CFR § 1.97. Accordingly, the information disclosure statement has being considered by the examiner. However, the listed patent applications are not suitable to be listed in PTO-1449, therefore, will not be published with the publication.

The Petition under 37 CFR § 1.59 will be considered and addressed by the concerned authority separately from this Office action.

The following rejections have been modified in view of the claim amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7, 9, 16-20, 24, 26, 28-33, 37, 39, and 41-45 stand rejected and the rejection have been modified under 35 U.S.C. 103(a) as being unpatentable over *Flanagan et al* (J Gen Virol 1997;78:991-7), *Seth et al* (PNAS 1998;95:10112), in view of *Hurwitz et al* (Vaccine 1997;15:533-40), and *Yu et al* (Genes Cells. 1997 Jul;2:457-66).

Amended claims are drawn to a *recombinant* Sendai virus vector encoding an immunodeficiency viral protein. Applicants argue that Hurwitz et al teach a wild type, but

not recombinant Sendai virus, thus the teaching is antithetical, and cannot be extrapolated to the treatment of other viruses, particularly those that are nonanalogous to PIV.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, the alleged deficiency is due to the claim amendment limiting the sendai virus to recombinant only, and can be cured by the teaching of *Yu et al*, who use a recombinant Sendai viral vector deficient in V gene encoding an HIV viral envelop protein, nonanalogous to PIV. Obviously, it is well known in the art that sendai virus could be used as a carrier for expressing a nonanalogous viral protein, particularly, immunodeficient virus.

Flanagan et al teach using a recombinant adenovirus expressing SIV Gag protein for vaccination in mice by intranasal inoculation, and teach that mucosal route of delivery is desirable. *Seth et al* teach using a vaccinia virus vector expressing gag-pol fusion polypeptides in multiple dosages (day 1 and 126) and inducing cytotoxic immune response specific to gag pol proteins in a rhesus monkey. *Hurwitz et al* teach the feasibility of intranasal multiple inoculation of a Sendai virus in African green monkeys (abstract, figures 1-4, and table 1). *Hurwitz et al* also teach the advantage of using Sendai virus as a potential human vaccine because its long-lasting effect stimulating memory B-cells as well as CTL response (last paragraph, page 539).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Flanagan et al* or *Seth et al*, *Hurwitz et al*, and *Yu et al* by substituting and/or combining the recombinant adenoviral or vaccinia vector with a recombinant Sendai viral vector and delivering such via intranasal inoculation with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention given the numerous carrier vectors known in the art, and all proven to be effective for mucosal vaccination for viral infection, it would have been obvious for the skilled artisan to select one of viral vectors having mucosal tropism such as the Sendai viral vector for developing a HIV or SIV vaccine as taught by *Flanagan et al*. Thus, the claimed invention as a whole was clearly *prima facie* obvious in the absence of evidence to the contrary. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Claims 11-13 and 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Flanagan et al* (J Gen Virol 1997;78:991-7), *Seth et al* (Proc Natl

Acad Sci USA 1998;95:10112-6), in view of *Kast et al* (J Immunol 1988;140:3186-93, IDS) and *Yu et al* (Genes Cells. 1997 Jul;2:457-66).

Applicants argue that *Kast et al* do not teach a recombinant sendai virus. The argument is not persuasive because the rejection is on the basis of combined teachings. The Kast reference is relied upon as a showing that sendai virus could effectively transduce dendritic cells, the transfected DCs are then capable of presenting the antigen to T cells inducing cytotoxic T lymphocyte activity.

Yu et al teach a Sendai virus vector encoding a virus protein (gp120) of the human immunodeficiency virus. *Yu et al* also teach that the vector system is active in mononuclear cells (T cells) and macrophage (APCs) and the vector could be used in immunological studies (abstract).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Flanagan et al* and *Kast et al*, by simply employ the vector taught by *Yu et al* and the viral protein taught by *Seth et al* with a reasonable expectation of success in inducing a specific cellular immune response. The ordinary skilled artisan would have been motivated to modify the method for their particular needs of investigation, i.e. a particular vector of interest, or a particular antigen of interest, etc. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claims 11-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Flanagan et al* (J Gen Virol 1997;78:991-7), *Seth et al* (Proc Natl Acad Sci USA

1998;95:10112-6), *Kast et al* (J Immunol 1988;140:3186-93, IDS), and *Yu et al* (Genes Cells. 1997 Jul;2:457-66) as applied to claims 11-13, and 15 above, further in view of *Boutillon et al* (US 6,015,564).

Claim 14 is drawn to using an autologous herpesvirus papio-immortalized B lymphoblastoid cell as the APC.

Applicants argue that Boutillon teach using HSV transforming B lymphoid cells, the disclosure does not cure the deficiencies of *Flanagan et al, Seth, Yu,* and *Kast et al.*

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, the *Boutillon et al* teaching is relied on for using herpes virus papio transforming B lymphoblastoid cells to make an immortalized cell line for CTL assay. It is the combined teachings as a whole that teaches the claimed invention.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Flanagan et al, Seth et al, Kast et al, and Yu et al*, by simply employ immortalized cells as taught by *Boutillon et al* with a reasonable expectation of success in inducing a specific cellular immune response. The ordinary skilled artisan would have been motivated to modify the method because the immortalized cells would be easier to care for. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-

1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
November 11, 2003

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

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